



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Justification of a Single Source Cooperative Agreement Award for the World Health

Organization

AGENCY: The Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response.

(Authority: Section 301 42 U.S.C. 241)

ACTION: Notice

SUMMARY: The U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR) intends to fund an unsolicited proposal submitted by the World Health Organization (WHO) to support work towards establishing a regulatory pathway at WHO for prequalification of medical countermeasures to be deployed internationally in an emergency, which includes supporting WHO and potential recipient countries to build regulatory capacity for the import, registration, and emergency use of medical countermeasures. The goals of this Cooperative Agreement are to: 1) Using smallpox vaccines as a case study, complete product review and prequalification of smallpox vaccines included in or pledged to the WHO Smallpox Vaccine Emergency Stockpile for emergency use; 2) Establish general regulatory pathways for emergency use authorization and/or a process for emergency prequalification of emergency medical countermeasures and; 3) Support potential recipient WHO member states in building capacities for the import, registration, and emergency use of medical countermeasures.

This Cooperative Agreement directly supports several federal initiatives focused on strengthening national and international health security, including HHS’s ongoing work within the Global Health Security Initiative (GHSI) to develop an operational framework for the international deployment of medical countermeasures which contemplates the legal, regulatory, and logistical issues to be considered during such a deployment as noted in the 2013 GHSI Ministerial communique.¹ Additionally, it supports Objective 9 of the Global Health Security Agenda² which calls for improving global access to medical and non-medical countermeasures during health emergencies and the improvement of international deployment capabilities. It also aligns with the HHS Global Health Strategy priority to “develop policy frameworks, agreements and operational plans to facilitate HHS decision-making in response to both single and multiple international requests for emergency assistance, including for the deployment of medical countermeasures and HHS personnel.”³

PERIOD OF PERFORMANCE: October 1, 2014 to September 29, 2017

FOR FURTHER INFORMATION: Please submit an inquiry via the ASPR Division of Grants Management at asprgrants@hhs.gov.

SUPPLEMENTARY INFORMATION: The Division of International Health Security within the Office of Policy and Planning in ASPR is the program office for this award.

¹ 2013 Global Health Security Initiative Ministerial Meeting Communique [online]. Available from: <http://www.ghsi.ca/english/statements.asp>

² The Global Health Security Agenda. Available from: <http://www.globalhealth.gov/global-health-topics/global-health-security/ghsagenda.html>

³ HHS Global Health Strategy Objectives [online]. Available from: <http://www.globalhealth.gov/global-programs-and-initiatives/global-health-strategy/strategy-objectives/>

Procedures for Providing Public Input: All written comments must be submitted no later than 15 days after posting of this announcement. Please submit comments to asprgrants@hhs.gov.

Dated: September 18, 2014.

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Assistant Secretary for Preparedness and Response.

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